2007 Highlights of Advances in the Pharmaceutical Sciences: An American Association of Pharmaceutical Scientists (AAPS) Perspective

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Abstract

The American Association of Pharmaceutical Scientists (AAPS) covers the full range of areas of expertise associated with the resolution of concerns pertaining to drugs and drug products. This editorial highlights the initiatives, issues, and challenges that are the forefront of the pharmaceutical sciences in 2007. It also provides an overview of how these difficult questions are being addressed through the programs and events associated with the AAPS 2007 Annual Meeting that will be held at the San Diego, California, Convention Center from November 11 to 15, 2007.

Keywords: dose predictions, product design, product quality control, population kinetics, dose individualization, regulatory sciences, pharmacostatistics, process analytical technology, medical imagining, quantitative pharmacology, dissolution, biotechnology

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Background

The pharmaceutical sciences reflect the integration of diverse areas of specialization for the purpose of creating a safe and effective therapeutic arsenal to support the health needs of human and veterinary patients. From bench top to bedside, the journey of any candidate molecule faces an array of complex issues, including the following:

- First-time in human dose predictions
- Product design
- Product quality control
- Evaluation of clinical safety and effectiveness in the patient population
- Getting the dose right (dose individualization)
- Premarketing and postmarketing regulatory controls for ensuring product quality, safety, and effectiveness, including the international harmonization of guidelines covering these activities
- The development of pharmacometric and pharmacostatistical methods that support all of the above

The American Association of Pharmaceutical Scientists (AAPS) encompasses the full range of areas of expertise

associated with the resolution of these concerns. AAPS fosters cross-disciplinary synergy among pharmaceutical scientists through the sponsorship of open forums for the exchange and dissemination of scientific knowledge, by fostering the education and career growth of members and recognizing individual achievement, by influencing the formation of public policy relevant to health and related issues of public concern, and by promoting the pharmaceutical sciences as they relate to health issues of public concern. Ultimately, AAPS cultivates an environment that promotes the development of creative solutions to the hurdles encountered as we take drugs from discovery to marketing.

To encourage idea exchange and interdisciplinary collaborations, AAPS is divided into 8 sections (or areas of specialization). These include:

- Analysis and Pharmaceutical Quality (APQ) Section
- Biotechnology (BIOTEC) Section
- Clinical Pharmacology and Translational Research (CPTR) Section
- Drug Design and Discovery (DDD) Section
- Pharmaceutics and Drug Delivery (PDD) Section
- Pharmacokinetics, Pharmacodynamics, and Drug Metabolism (PPDM) Section
- Pharmaceutical Technologies (PT) Section
- Regulatory Sciences (RS) Section

In addition to these sections, AAPS members with a common interest in a specific discipline can convene a focus group with the intent of promoting emerging new areas of interest. Oftentimes, it is within these focus groups that the "hot" issues in pharmaceutical sciences are identified and that programming is created. Scientific leaders may also elect to spearhead initiatives that will change the way that drug products are developed and regulated.

Two recent examples of such AAPS initiatives are QXology and the D3I. QXology provides a systems biology approach to drug development, integrating the relationships between disease state, patient prognostic factors, drug characteristics, and safety and efficacy outcomes. Under the leadership of individuals such as Sandy Allerheiligen, Bob Powell, Joga Gobburo, and Jeff Barrett, the goal of QXology is to provide explicit, transparent, and predictive evidence for optimizing drug discovery and development, and for delivering knowledge that enables quantitative decision making. AAPS is sponsoring a workshop on this topic (AAPS Workshop on Quantitative Pharmacology: A Roadmap for Rational, Model-based Drug Development), which is scheduled to occur immediately preceding the 2007 AAPS annual meeting.

The Drug Discovery and Delivery Interface (D3I) Task Force is laying the foundation to enable AAPS to better address issues of lead selection, lead optimization, and drug candidate selection at the interface before traditional product development activities. D3I brings together scientists across the various AAPS sections and focus groups who work with medicinal chemists and biologists to incorporate druglike properties into new molecular entities, thereby reducing the risk for attrition during product development. D3I seeks active involvement in AAPS from those sister organizations within which these discovery scientists are typically members. As part of the 2007 annual meeting, AAPS will convene a half-day symposium to introduce D3I concepts. Among the presentations, Ron Borchardt will discuss the conceptual origins behind the formation of the D3I effort and. Scott Grossman will discuss the implementation of D3I concepts in an industrial setting (Michael Hageman, personal communication, April 2007).

In addition to these state-of-the-art initiatives, AAPS will be collaborating with the Society of Non-Invasive Imaging in Drug Development (SNIDD), which is an institute of the Academy of Molecular Imaging.[1] Working jointly, AAPS and SNIDD will be exploring the use of medical imaging in drug discovery and development. The importance of this technology is underscored by the dramatic changes in the drug discovery and development model that have occurred over the past decade. From discovery to marketing, the process takes longer, costs are higher, and fewer drugs are approved, making it difficult and in some cases nearly impossible to recoup the investment. For this reason, companies that will survive in this new environment must find innovative methods to identify viable product candidates, condense development processes, reduce costs, and create value for drugs to be marketable. One proven and very efficient method to succeed in this new environment is through the use of medical imaging in drug discovery and development programs. With this in mind, 2 programs will be scheduled on this topic during the 2007 annual meeting. On Tuesday, November 13, the CPTR section will sponsor a sunrise session titled "Imaging Technology and Clinical Target Site PK and PD Assessments: Emerging Opportunities and Potential Limitations." This will be followed by the AAPS/SNIDD collaborative hot topic session titled "Imaging Options to Survive in the New Drug Development Environment" from 12 to 1:15 pm. This Hot Topic Session will focus on a review of imaging options and will highlight examples of how imaging has reduced development time, costs, and added value to compounds (Donald Head, Larry Fleckenstein, and Joanne Lockwood, personal communication, April 2007).

It is these kinds of collaborations within and between organizations that exemplify the benefits provided to our AAPS membership through our various electronic communications, Distance Learning, and networking opportunities, and in

our meetings and expositions. As a leading pharmaceutical science organization, AAPS strives to keep its members informed on new scientific directions and state-of-the-art technologies. Accordingly, the AAPS Annual Meeting provides lively and insightful discussions of the day's most pressing topics.

By examining the evolution of subject matter covered in these meetings over time, we can map the changes in scientific directions. Therefore, using the programming of the 2007 AAPS Annual Meeting as a backdrop, each section was asked to address the following questions:

- Who are you?
- As reflected in your 2007 section-sponsored programs, what are the current "hot topics" within your field?
- What do you envision will be the changes in the landscape of your discipline over the next 5 years?

Section Responses

Analysis and Pharmaceutical Quality Section

The Analysis and Pharmaceutical Quality (APQ) Section is composed of members whose interests are in the areas of analytical methods development for bulk drug substances, as well as drugs in pharmaceutical dosage forms and biological fluids, and methods and procedures for assuring that quality is designed into pharmaceutical products. The programming for the 2007 AAPS Annual Meeting reflects our broad spectrum of interest and demonstrates the significant impact of analysis and pharmaceutical quality on all aspects of pharmaceutical sciences. The 2007 APQ program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/APQ-2007-programhighlights.pdf.

Today's primary challenges are encompassed by the need to characterize the physicochemical properties of new drug candidates rapidly, to understand how these variables control the biological effect of these compounds, and to apply this understanding to ensure product consistency throughout its market life. Considering the speed with which the industry is moving and the need for cost-effective methods for product quality control, novel analytical methods emerge. In turn, the performance of these methods must be characterized and validated.

The next 5 years will see a continued emphasis on sample throughput and minimization of sample required. We will see the further emergence of parallel processing and multiple analyte techniques. In the bioanalytical arena there will be a convergence of the measurement and the informatics steps. There will also be continued development of analytical technologies that support quality by design (QbD). These advances will occur within the regulatory constraints discussed at the 2007 Annual Meeting.

Biotechnology Section

The Biotechnology (BIOTEC) Section provides a dynamic international forum for the exchange of biotechnology-related knowledge among scientists to enhance their contributions to health. This includes the discovery, development, and manufacture of biotechnology-related pharmaceutical products and therapies gained through advances in science and technology. We offer timely biotechnology-related scientific programs, ongoing education, opportunities for networking, and professional development.

Over the past year, we have seen the field of biotechnology continue to expand at a rapid pace. Several technologies continued their march through clinical development toward commercialization including viral and nonviral gene therapy[2] and new stem cell treatments. New biological adjuvants[3] are also proceeding through clinical development. Protein therapies and monoclonal antibodies[4] are expanding in application as a result of improved therapeutic efficacy and host cell production capacity. The need for improved delivery, production, and immunogenicity and biomarker assessment continue to expand as well. These areas of intense activity are reflected in our AAPS 2007 Biotechnology Conference (www.aapspharmaceutica.com/meetings/biotec/bt07/index.asp) and in the programming scheduled for November at the AAPS 2007 Annual Meeting.

The 2007 BIOTEC program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/BIOTEC-2007-programhighlights.pdf.

In the next 5 years, the field of biotechnology will continue to move forward in several areas. Many new drug products will enter the marketplace, including new monoclonal antibodies, protein therapies, and genetic treatments. Viral and nonviral DNA, siRNA, and new stem cell treatments may also reach the market. Increased production capacity will be added through increased numbers of biological manufacturing facilities and increased host cell production techniques. As the field of biotechnology advances, support areas such as those encompassed in the other sections, will need to proceed in parallel. This will raise a host of new challenges as the science evolves from a paradigm focused on small molecules to one inclusive of large molecules.

Clinical Pharmacology and Translational Research Section

The Clinical Sciences Section has recently changed its name to the Clinical Pharmacology and Translational Research (CPTR) Section to better reflect the membership within the section and to further distinguish ourselves from other sections in AAPS. Our members represent diverse background and training, including clinicians and basic scientists.

Clinical pharmacology is the application of pharmacology to humans. One definition of translational research is "testing, in humans, novel therapeutic strategies developed through experimentation," the so-called "Bench to Beside" paradigm, the thrust of which are phase I trials.[5] Therefore, in short, our section is interested in the transition of basic science to the clinic and the rational use of drugs in humans. The mission of the CPTR section is to provide "a dynamic forum for the exchange of knowledge among scientists to enhance their contributions to innovative, science-based solutions for development and rational use of human pharmaceuticals."[6]

Because of the multidisciplinary nature of CPTR, our interests align with many sections within AAPS. It is our belief that clinical sciences are currently in a state of flux as drug development moves from a "one-size-fits-all approach" to more personalized medicine where dosing is based on patient-specific factors. We further believe that drug development is moving from an empirical approach to a more rational, mathematically based approach where modeling and simulation of exposure-response data play increasing roles in achieving speed to market and for finding "the right dose at the right time in the right patient."

Several recent publications illustrate these beliefs. Latz et al presented a series of papers on the population pharmacokinetics-pharmacodynamics of a new anticancer agent, pemetrexed (Alimta), which is approved as a single agent for the treatment of non-small cell lung cancer. Their first manuscript[7] showed that renal function–based dosing resulted in more than 90% of the patients being within 25% of the target area under the curve (AUC). In contrast, fewer than 75% were within 25% of the target AUC using a body surface area-only or fixed dose approach. Their second paper[8] developed a pharmacodynamic model for neutrophil counts using a cell-transit model. They also took the approach of examining the influence of covariates on the parameters in the transit model, something not usually done with these types of models. Their final paper[9] used correlation analysis to examine how exposure measures affected the grade of neutropenia, the time to nadir, and the recovery time. They also used simulation to show that for a typical patient taking the label dose of 500 mg/m^2, there is a 50% chance that the patient would remain at grade 0 neutropenia under the Common Toxicity Criteria. However, there was only a 25% chance of grade 0 neutropenia if the dose was increased to 600 mg/m^2. These papers nicely demonstrate the power of a well-developed population pharmacokinetic-pharmacodynamic model, combined with simulations, to answer questions about optimal dosing and the influence of patient covariates on drug toxicity.

As reflected by the diverse nature of translational research and the diversity of our section members, the programming for 2007 is just as varied and covers many different topics. A summary of programs sponsored by the CPTR section for the 2007 Annual Meeting is provided below. The 2007 CPTR program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/CPTR-2007-programhighlights.pdf.

Resistance to CPTR concepts continues to exist within pharmaceutical companies. Therefore, we envision that industry-wide application of personalized approaches in clinical medicine and the routine use of such information in making pharmacotherapy decisions are perhaps 20 years away. Our vision is that within the next 5 years, we expect to see these barriers collapse as there is an ever-growing emphasis on the use of genetic and patient-specific information requested from the US Food and Drug Administration (FDA) to support product approval and clinical data evaluation, and from the medical community to support dosage optimization.

Drug Design and Discovery Section

The Drug Design and Discovery (DDD) Section serves as the preeminent forum among pharmaceutical scientists engaged in at the forefront in the design, discovery, manipulation, and optimization of lead medicinal and therapeutic agents.

Drug design and discovery continues to play a dominant role in the pharmaceutical industry, providing the central foundation of new chemical entities (NCE) for the pursuit of druggable candidates for clinical development. These NCEs are created in academia, industry, and research institutions using traditional methods and modern technologies that relate chemical structure (and the subsequent modification of that structure) to the pharmacological activity of small molecules and macromolecules. The DDD Section strives to serve the needs of medicinal and natural products chemists, and scientists engaged in emerging technologies and in disciplines involved in drug product development, including the manipulation and optimization of structural hits and leads (druggability).

The importance of the synergy we foster between disciplines in the pharmaceutical sciences is keenly evident in the programming initiated and sponsored by the DDD for the AAPS 2007 Annual Meeting. First and foremost, we continue to showcase our future pharmaceutical scientists in a graduate student poster/podium awards symposium. From all the abstracts that are submitted to our section, up to 4 students are annually selected to present their work. With an eye on the rapid pace at which drug design and discovery occurs, these poster/podium sessions enable us to provide AAPS members with late-breaking and cutting edge research from our academic and research institutions through this mechanism. Indeed, it is great to come and support our

future colleagues and encourage excellence through our award programs and the other various DDD-sponsored Annual Meeting programs. The 2007 DDD program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/DDD-2007-programhighlights.pdf.

As members of the DDD Section, we predict that, in years to come, our involvement in initiatives supporting drug product development will gain an increasing level of importance as pharmaceutical scientists strive to embrace concepts such as D3I and QXology. With technological advances continuing forward at a rapid pace, drug discovery has also accelerated. It is a great time to be a pharmaceutical scientist and the future looks very promising as more and more novel targets are identified and mechanisms to combat disease are more understood.

Pharmaceutics and Drug Delivery Section

The Pharmaceutics and Drug Delivery (PDD) Section is mostly responsible for informing and updating the AAPS members of current issues on physical pharmacy, formulation, drug delivery, and regulatory affairs pertaining to these areas. This section also provides a platform for thousands of formulation, drug delivery, and regulatory scientists from academia, industry, and government agencies to interact and share their individual and collective vision on global pharmaceutical research topics via different communication channels, including the annual AAPS meeting. The PDD Section fosters the communication of many of these current and hotly researched topics that would significantly benefit our large and still growing national and international membership.

The AAPS PDD section is sponsoring 12 scientific programs in the upcoming 2007 Annual AAPS meeting and will be cosponsoring 11 additional programs (most of which are organized in collaboration with PT and PPDM). In addition to sponsoring and supporting the scientific programs, the PDD section has reviewed and accepted hundreds of high-quality research abstracts. The poster session will provide meeting attendees a unique overview of the state-of-the-art research associated with pharmaceutics and drug delivery.

As highlighted in our program for the AAPS 2007 Annual Meeting (see below), the scope of issues addressed within our section is truly a reflection of the current trends in pharmaceutical research. As molecules with poor bioavailability are developed, alternative technologies for drug delivery are required. Thus, the current hot area of research is the formulation of nanoparticles and excipients that can facilitate drug absorption. Piggybacking on these issues are concerns about ensuring product quality, particularly in view of high production demands and cost constraints. Accordingly, Quality by Design (QbD) and Process Analytical Technology (PAT) are in the forefront of our attention. Along with these technologies come the complicated statistical methods that are needed to interpret data generated with these methods. The 2007 PDD program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/PDD-2007-programhighlights.pdf.

The development of nanotechnology and targeted drug delivery systems, and the understanding of mechanisms to facilitate the absorption of complex molecules will continue to be of fundamental concern over the next 5 years. In addition, the importance of quality by design, and creating cost-effective technologies for process control will increase over time, particularly as biotechnology products give rise to new formulation and stability challenges. With these points in mind, over the next 5 years, we envision an ever-growing push for collaboration among the pharmaceutical sciences, with PDD serving as a central hub for identifying key issues that need to be addressed.

Pharmacokinetics, Pharmacodynamics, and Drug Metabolism Section

The Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM) Section serves as an international forum to examine issues related to the biopharmaceutics, pharmacokinetics, pharmacodynamics, drug metabolism, and transport of pharmaceutical products and therapies. PPDM brings together individuals whose research interests include characterization of drug and chemical actions, disposition, and biotransformation at the organism, tissue, cellular, and subcellular levels. The section provides an opportunity for networking, presentation of new data, and an exchange of ideas by individuals actively engaged in various facets of pharmacokinetics, pharmacodynamics, drug metabolism and transport, biopharmaceutics, and related sciences. This scientific exchange enables scientists from academia, industry, and regulatory agencies to improve/develop better patient therapies while jointly advancing their professional development and respective disciplines.

As reflected in our programming for the 2007 AAPS Annual Meeting, the timely topics in our discipline include the influence of transporters and metabolizing enzymes on drug exposure, the impact of these factors on drug-drug interactions (and how to identify the potential for these interactions), the development of in vitro–in vivo correlations for both oral and parenteral dosage forms, the application of preclinical studies as a component of lead candidates assessment, getting the dose right through clinical pharmacokinetic (PK) and pharmacodynamic (PD) modeling and simulation techniques, and the application of bioequivalence in the development of final market

formulations. Because current research issues are complex, PPDM recognizes the need for education and for the training of new scientists through active recruitment of new students and postdoctoral fellows, support of graduate faculty, and encouraging student participation within PPDM. To address these section goals, educational sunrise sessions and a Graduate Student Research Symposium, featuring award-winning graduate student presentations (on Tuesday morning) are included in the section programming. The 2007 PPDM program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/PPDM-2007-programhighlights.pdf.

Considering the current momentum in drug design and discovery, in addition to the ever-growing role of large molecules as a component of our therapeutic arsenal, the next 5 years will likely involve the development of new technologies for measuring the active moiety at the site of action, therapeutic predictions based on QXology, and increasing our understanding of interspecies differences to enhance our ability to capture human PK and PD of complex molecules through the use of animal models.

Pharmaceutical Technologies Section

The Pharmaceutical Technologies (PT) Section is a leading global organization for scientists and technologists involved in the research, design, development, and manufacture of drug delivery systems. It strives to advance the pharmaceutical sciences by

- Providing a forum for the open interchange and dissemination of scientific knowledge in the research, design, development, and manufacture of dosage forms and drug delivery systems;
- Promoting the continued growth and development of pharmaceutical science and technology;
- Fostering graduate education, career growth, and professional development of the membership;
- Recognizing excellence in individual achievements and professional contributions; and
- Collaborating with and supporting other AAPS sections, focus groups, and other professional/scientific organizations.

Within the recent past, research in the area of pharmaceutical technologies has primarily focused on early characterization of drug substance, new analytical technologies for preformulation science, implementation of Process Analytical Technologies (PAT) for enhanced process understanding, and functionality testing of excipients for robust product design. These issues are captured in our 2007 Annual Meeting programming where they are addressed not only from the perspective of the technology itself but also in terms of its applicability to nutraceuticals, pediatric formulations, and drug products intended for alternative routes of delivery (eg, inhalation therapy).

The Annual Meeting will also attract internationally renowned pharmaceutics and drug delivery scientists for the purpose of examining today's most challenging problems during our outstanding scientific programs. In addition, the PT section has reviewed and accepted hundreds of high-quality research abstracts. The poster session will provide the meeting attendees with a unique overview of the latest and most advanced research topics in pharmaceutics and drug delivery. Meeting participants will also have the opportunity to view the posters and interact with the authors of the contributed poster sessions throughout the meeting. The 2007 PT program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/PT-2007-programhighlights.pdf.

We envision that in the next few years, research will further focus on "intelligent" formulation design and manufacturing process for drug products. Pharmaceutical companies will devote more resources and use newer technologies to better understand not only the drug substance but also functional excipients. More research is expected in the area of PAT to better understand the manufacturing process and to build higher quality into the product. The industry would use the concept of design space to have a robust product design and manufacturing process. A continued push for faster development of lead candidate will result in a more vigorous effort to characterize the drug substance early in development. Last, refinement of existing controlled release technologies and exploration of new drug delivery methodologies are likely to continue.

Regulatory Science Section

Regulatory science (RS) is the strategic compilation of multidisciplinary information on product performance as it pertains to safety, efficacy, and quality. It represents a complex integration of research that is aimed at bridging the gap between scientific research and regulatory (policy and legality) challenges. Regulatory science also encompasses issues pertaining to regulatory affairs: the development of science-based regulations that help agencies better meet the needs of protecting public health and environmental safety, the international harmonization of these regulations, and ensuring the availability of safe and effective pharmaceuticals. The mission of our section is to obtain scientifically sound resolutions for complex regulatory issues, optimize scientific approaches to product development, and provide input into the development of science-based regulations and guidance for registration of new pharmaceuticals worldwide.

Because we reflect the integration of science and policy, our areas of greatest focus reflect both the state-of-the-art science as well as international social, political, and economic concerns. As our therapeutic arsenal evolves and as the philosophy of therapy changes (eg, the current trend toward individual dose optimization or personalized medicine), the laws and regulations needed to ensure that medicinal products meet the expectations of the medical community and the patient consumer needs to evolve accordingly. As new manufacturing and quality control methods are developed, regulatory guidance is necessary to clarify expectations on the information required in a product dossier. Therefore, in many ways, regulatory science is the one area that touches on each and every aspect of the drug product development process.

As seen in our 2007 RS-sponsored programming, this past year has largely focused on manufacturing issues (eg, QbD and PAT). Drug-device combinations remain a challenge because the science is complex and clearly defined regulatory guidance is not as yet available for these products. The explosion of interest in large molecules has raised a host of regulatory issues for which we are not as yet prepared. For example, how do we characterize biological products, how do we set expiry dates on these products, is it possible to develop a generic alternative to a large molecule that is off patent? Highlights of our 2007 Annual Meeting programming are provided below. The 2007 RS program highlights are available at: www.aapspharmaceutica.com/publications/pdfs/RS-2007-programhighlights.pdf.

As novel drugs and delivery systems become incorporated into our therapeutic arsenal, we expect to observe an entirely new set of regulatory challenges facing industry and regulators. As seen in some of the initiatives being forwarded by all sections at the 2007 Annual Meeting, the rising costs for drug development will lead to the creation of new innovations and technologies to improve efficiency and reduce cost. These changes are accompanied by the need for creating systems for quality control, performance validation, and data interpretation that can applied in the regulatory arena. This will prove to be no easy task. Paralleling these challenges will be the continued pressure for product globalization and the international harmonization of regulatory requirements. Finally, while times are certainly exciting, there is the need for increasing vigilance as we face new public health threats, be they due to human error, new diseases, the unknowns associated with novel molecular entities/excipients/delivery systems, or ongoing threats to our own national security. To address these issues, the regulator, the practitioner, the scientist, and the patient must cooperate as we seek creative solutions to the therapeutic challenges we face today and will be facing tomorrow.

Concluding Comments

The challenges facing the pharmaceutical sciences are expanding over time as we seek to address increasingly complex medical needs and health care expectations. With this complexity comes an ever-expanding need for synergy among diverse areas of expertise. For this reason, the opportunity to establish collaborative networks among the scientific thought leaders is essential if we are to meet the growing needs and expectations of the patient and the medical community.

The agenda for the AAPS Annual Meeting reflects emerging technologies and the most pressing issues currently affecting the pharmaceutical sciences. For that reason, whether the program is formatted as a roundtable or symposium, time is allotted for discussion and debate. The fundamental difference between these 2 events is that symposia allow for formal presentations, whereas roundtables are formatted for more focused discussions with only limited time allocated for presentations. Approximately 2000 research abstracts are accepted as posters each year, thereby allowing both seasoned veterans and young scientists to showcase their research and to explore perspectives on their work with others. Posters covering the most pressing topics are selected for presentation at the poster-podium sessions.

In 2007, the AAPS Annual Meeting will be held at the San Diego, California, Convention Center from November 11 to 15, 2007. Annual Meeting events begin as early as 7 am (the Sunrise Sessions) and continue through 5 pm. In the evenings, section-sponsored social gatherings promote networking opportunities. Daily availability to visit the Exhibition Hall extends educational opportunities by providing extensive displays of state-of-the-art technology and the chance to interact with experts across a variety of research support companies.

For more information regarding the 2007 program and for registration materials, go to www.aapspharmaceutica.com/meetings/annualmeet/am07/index.asp. We also invite you to learn more about AAPS at our Web site www.aapspharmaceutica.com.

References

1. Society of Non-Invasive Imaging in Drug Development. Available at: http://www.snidd.org/. Accessed April 30, 2007.

2. Rana TM. Illuminating the silence: understanding the structure and function of small RNAs. *Nat Rev Mol Cell Biol*. 2007;8:23-36.

3. Pascual DM, Morales RD, Gil ED, Munoz LM, Lopez JE, Casanueva OL. Adjuvants: present regulatory challenges. *Vaccine*. 2006;24:S88-S89.

4. Melero I, Hervas-Stubbs S, Glennie M, Pardoll DM, Chen L. Immunostimulatory monoclonal antibodies for cancer therapy. *Nat Rev Cancer*. 2007;7:95-106.

5. Marincola FM. Translational medicine: a two-way road. *J Translational Med*. 2003;1:1-2.

6. About the Clinical Pharmacology and Translational Research (CPTR) Section Goals and Mission. Available at: http://www.aapspharmaceutica.com/inside/sections/cptr/about/goals.asp. Accessed May 11, 2007.

7. Latz JE, Chaudhary A, Ghosh A, Johnson RD. Population pharmacokinetic analysis of ten Phase II clinical trials of pemetrexed in cancer patients. *Cancer Chemother Pharmacol*. 2006;57:401-411.

8. Latz JE, Karlsson MO, Rusthoven JJ, Ghosh A, Johnson RD. A semimechanistic-physiologic population pharmacokinetic/pharmacodynamic model for neutropenia following pemetrexed therapy. *Cancer Chemother Pharmacol*. 2006;57:412-426.

9. Latz JE, Rusthoven JJ, Karlsson MO, Ghosh A, Johnson RD. Clinical application of a semimechanistic-physiologic population PK/PD model for neutropenia following pemetrexed therapy. *Cancer Chemother Pharmacol*. 2006;57:427-435.